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excess of the amounts allowable under this subpart.

NOTE: The Secretary may waive any limitation on reimbursement imposed by subpart F of this part for experiments conducted under section 402 of Pub. L. 90–428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92–603, and under section 222(a) of Pub. L. 92–603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 66 FR 3176, Jan. 12, 2001]

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

- (a) *Scope*. This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:
- (1) State government-owned or operated facilities (that is, all facilities that are owned or operated by the State.)
- (2) Non-State government owned or operated facilities (that is, all government operated facilities that are neither owned nor operated by the State).
- (3) Privately-owned and operated facilities.
- (b) General rules. (1) Upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.
- (2) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.
- (c) Exceptions. Indian Health Services and tribal facilities. The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).
- (d) Compliance dates. Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in para-

graph (b)(1) of this section by one of the following dates:

- (1) For non-State government-owned or operated hospitals—March 19, 2002.
- (2) For all other facilities—March 13, 2001.

[66 FR 3176, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2611, Jan. 18, 2002; 72 FR 29835, May 29, 2007; 75 FR 73975, Nov. 30, 2010; 77 FR 31513, May 29, 2012]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

§ 447.342 [Reserved]

PREPAID CAPITATION PLANS

§ 447.362 Upper limits of payment: Nonrisk contract.

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

- (a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to beneficiaries: plus
- (b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

RURAL HEALTH CLINIC SERVICES

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in §440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in §440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral

part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.

- (b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.
- (c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:
- (1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.
- (2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.
- (3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.
- (d) For purposes of paragraph (c) (1) and (3) of this section, "visit" means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suf-

fers illness or injury requiring additional diagnosis or treatment.

 $[43\ FR\ 45253,\ Sept.\ 29,\ 1978,\ as\ amended\ at\ 51\ FR\ 34833,\ Sept.\ 30,\ 1986]$

Subparts G-H [Reserved] Subpart I—Payment for Drugs

Source: 72 FR 39239, July 17, 2007, unless otherwise noted.

§ 447.500 Basis and purpose.

- (a) Basis. This subpart—
- (1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.
- (2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physicianadministered drugs.
- (3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.
- (b) *Purpose*. This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

Bona fide service fees mean fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level)